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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,943	10/31/2003	Klas Stoltz	STOLTZ11	8947

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,943

Applicant(s)

STOLTZ, KLAS

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 1 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on n/a is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. The examiner notes the identification of this application as a national stage filing under 35 U.S.C. 371 based on PCT/SE02/00951 filed on 07/05/2002.
2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Sweden on 05/17/2001. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Election/Restrictions

3. The examiner notes the Election/Restriction requirement mailed 04/18/2006 is withdrawn as this application is identified as a national stage filing under 35 U.S.C. 371 based on PCT/SE02/00951 filed on 07/05/2002.

Information Disclosure Statement

4. The information disclosure statement(s) (IDS) submitted on 02/09/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Drawings

5. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sampling device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The abstract of the disclosure is objected to because excessive length (>150 words). Correction is required. See MPEP § 608.01(b).

Claim Objections

8. Claims 1 and 5 are objected to because of the following informalities:
9. The term "substantial" and variants thereof is a relative term that appears to render the claims indefinite. The term "substantial" and variants thereof is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For claim 1, the magnitude of the underpressure is unclear. For claim 5, the geometrical configuration of the bulb is unclear.
10. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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12. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner notes a single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph. For example in the instant case, the positive recitation of the limitation "which allows a sample of the body substance to enter the capsule through at least one inlet opening which is opened in a predetermined position of the digestive tract following contact with the body substance to be collected" appears to claim steps involved in the process of using the apparatus.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551. See MPEP 2173.05(p).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pawelec (US 4,481,952). Pawelec discloses a swallowable, digestive-fluid sampling capsule (G) as best seen in Figures 12 and 13, comprising:

- a capsule wall (1) defining at least one inlet opening (17);
- an inner chamber (18) defined by said capsule wall operable effective to hold vacuum or negative pressure said inlet opening is sealably engaged; and
- a blocking member (9) disposed in said inner chamber adjacent to said inlet opening in said capsule wall,
- wherein said blocking member comprises an elastic material that is operably configured to (a) permit fluid flow of a body substance into said inner chamber as long as a pressure difference exists between said inner chamber and an external environment of the capsule following contact with the body substance and (b) prevent fluid flow through said inlet opening from the inside of the chamber to the exterior environment when said pressure difference has been equalized.

17. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein said inlet opening is sealed by a plug member (28) of a material that is dissolved following contact with said body substance.

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18. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein said blocking member consists of an elastic, operably self-sealing membrane, which in a fluid flow preventing configuration sealingly bears on the inside of said capsule wall effective to prevent an outflow of the body substance in the inner chamber.

19. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein said capsule comprises two members, a cap member (46a) and a body member (46b) that are permanently joined to each other and disposing said blocking member therein.

20. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein said blocking member is substantially bulb-formed and has at least one laterally located aperture (16) to establish fluid communication of a body substance with said inner chamber.

21. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein a peripheral edge of said blocking member is disposed between said cap member and said body member as best seen in Figures 12 and 13.

22. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein said plug member consists of two or more layers of different dissolvable materials (column 1 lines 8-64).

23. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein a filter (12) is disposed between said cap member and said body member.

24. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein protrusions (the enlarged portions of element 14) are externally disposed on said

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capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves as best seen in Figures 12 and 13.

Conclusion

25. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Gu et al (US 5,971,942) discloses an intestinal fluid sampling device comprising two half sections with a readily dissolvable seal effective to prevent and permit fluid flow under varying environmental conditions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JGH *JH*

Max F. Hindenburg
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